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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,817	09/22/1999	JAMES P. KOCH	01996/005001	3842

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BOSTON, MA 02110

EXAMINER

BROWN, MICHAEL A

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/400,817

Applicant(s)

James P. Koch

Examiner

Michael Brown

Group Art Unit

5764

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/27/04
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-3, 5-6, 8-17, 19-36, 37-50 and 57-61 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 28-32 and 57 is/are allowed.
- ☒ Claim(s) 1-3, 5-6, 8-17, 20-25, 27, 33-35, 38-48 and 58-59 is/are rejected.
- ☒ Claim(s) 19, 26, 49-50 and 60-61 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 26
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 10-11, 44-46 and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp, as set forth in the previous office action, paragraph no. 2, Paper No. 25.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 2 above, and further in view of Cox, as set forth in the previous office action, paragraph no 3, Paper No. 25.

Claims 8-9, 12-13, 15, 17, 20, 22-25, 27, 41-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp, along with Shields, as set forth in the previous office action, paragraph no. 4, Paper No. 25.

Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Petrus, as set forth in the previous office action, paragraph no. 7, Paper No. 25.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-36, 39-40 and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goepp.

Allowable Subject Matter

Claims 19, 26, 49-50 and 60-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 28-32 and 57 are allowed.

Response to Arguments

Applicant's arguments filed February 27, 2004 have been fully considered but they are not persuasive. Applicant argue that Lipfert does not disclose a rim member that is the same as the rim member disclosed in the present invention. However, a rim member is all that is claimed in claim 1. Applicant has not claimed any additional structure, simply a rim member. Applicant argues that Lipfert does not disclose a cervical cap made of a cured polymeric material and having the ability to custom fit the device to the patient's cervix. However, Lipfert was used to set forth the environment of a cervical cap. Goepp was used as a modifier to make the cervical cap of a cured polymeric material and a rim that custom fits the exocervix. Applicant argues that there is no motivation for combining Lipfert and Goepp. However, as set forth above, both devices are cervical caps. Goepp teaches using a rim member to fit the device to the exocervix. The device disclosed by Goepp is made of a cured polymeric material.

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Cleary, Goepp provides the two additional structural limitations not disclosed by Lipfert. Applicant argues that Goepp does not disclose the kit recited in claims 33-36, 39-40 and 51. However, Goepp discloses a cervix cap having a rim member, shaped to fit the exocervix. The cap is made of a curable polymeric material. The device is a shell.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

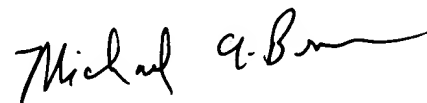
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 703-308-2682. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Brown
May 28, 2004



MICHAEL A. BROWN
PRIMARY EXAMINER